AUG 30 2005

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ATTN: BRIAN D. GILDEA, ESQ.
500 OLD CONNECTICUT PATH
FRAMINGHAM, MA 01710

In re Application of
Hyldig-Nielsen et al
Serial No. : 09/593,914
Filed : 14 June 2000
Attorney Dkt No. : BP9901-US

Decision on Petition

This is in response to the petition under 37 CFR 1.144 or 1.181 filed 22 July 2005, to request review of a restriction requirement.

BACKGROUND

Review of the file history shows that the application was filed June 14, 2000 under 35 U.S.C.111(a). The application as filed contained 85 claims.

On January 15, 2002 the examiner mailed a first Office action on the merits, which included a restriction requirement requiring applicants to elect a single nucleotide sequence for examination. Applicants had elected (telephonically) SEQ ID No: 1. In response, the examiner withdrew claim 34 from consideration and limited examination of the remaining claims to the elected sequence.

On February 19, 2002 applicants filed a response in which the restriction requirement was traversed on essentially the same grounds argued in this petition.

On July 17, 2002 the examiner mailed an Office action in which the restriction requirement was made final. A final rejection was mailed February 25, 2003.

On August 25, 2003 applicants filed their first petition under 37 CFR 1. 144, to withdraw the restriction requirement set forth by the examiner which was DENIED.

Applicants filed an appeal brief on February 18, 2004.

On April 27, 2004, applicants filed a new petition under 37 CFR 1. 144, to withdraw the restriction requirement set forth by the examiner and filed a supplemental Appeal Brief on May 20, 2004.

On August 3, 2004 their petition was GRANTED because the restriction requirement between Groups 1-Xl was inadequately set forth, and because the Examiner failed to identify, address or properly treat the linking claims. The restriction requirement between Group 1-Xl was withdrawn.

On October 26, 2004, Examiner reopened the prosecution and again restricted the claims in to eleven groups each based on a single SEQ ID NO. On December 1, 2004, applicants elected with traverse Group I directed to SEQ ID NO: 1.

In response, the examiner withdrew claim 34 from consideration and examined the remaining claims to the elected sequence, there being no allowable linking or generic claim, in the Office action mailed on March 10, 2005.

On 22 July 2005, Applicants petitioned again to review the restriction requirement to restrict the claims to a single set of probes.

DISCUSSION

The application, file history and petition have been considered carefully.

Applicant raised several concerns in the petition.

(a) Applicants correctly point out that the restriction requirement is based upon 35 USC 121.

(b) Applicants are correct in stating the reasons for distinction between the probes having SEQ ID NOs 1-11: they are considered to be unrelated since each of the claimed sequences are structurally and functionally distinct from each other. Applicants suggest that the search would not be a burden because all of the inventions are classified in Class 536, subclass 24.32 and Class 435, subclass 6. MPEP 808.02(C) points to a different field of search as grounds for establishing burden if restriction is to be required. It is noted that the literature and sequence database search is more pertinent than class and subclass searches for inventions claimed by polypeptide or polynucleotide sequences. Furthermore, it is unlikely that applicants would accept prior art obtained by a search for one sequence in a rejection over a second sequence.

(c) Applicants are correct that the Office must follow statute and judicial precedent.

(d) Applicants point to *In re Weber*, 580 F.2d, 455, 459, 198 USPQ 328 (CCPA 1978) to argue that the restriction requirement was improper and point to the following text in MPEP 803.02.

> Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper

for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

(e) Applicants argue that it is acceptable for a Markush-type claim to have independent and distinct inventions and that the examiner should have set forth an election of species and not a restriction requirement.

(f) Applicants also point to *In re Harnisch* and MPEP 2173.05(h) to argue that the proper test for whether SEQ ID NOs 1-11 are distinct is whether they share a common utility. Applicants state that the PNA probes are useful for detecting *Dekkera/Brettanomyces* yeast (a group of yeasts associated with the spoilage of wine).

Before addressing the concerns (d), (e) and (f) of the petition, it is noted that no claims are currently pending which are limited to the elected inventions. Claim 10 is set forth below as a representative independent claim under examination.

10. (Previously Amended) An enzyme-linked probe for detecting, identifying or quantitating the presence of *Dekkera/Brettanomyces* yeast in a sample of interest, wherein the probe comprises a probing nucleobase sequence wherein at least a portion of the probing nucleobase sequence is at least ninety percent homologous to the nucleobase sequences selected from the group consisting of: AGC-GGG-TCT-ATT-AGA (Seq. ID No. 1); CCA-GGT-GAG-GGT-CGC (Seq. ID No. 2); CGG-TTG-CCC-GAT-TTC (Seq. ID No. 3); TCG-CCT-TCC-TCC-TCT (Seq. ID No. 4); CGG-TCT-CCA-GCG-ATT (Seq. ID No. 5); CAC-AAG-ATG-TCC-GCG (Seq. ID No. 6); GCG-GGC-ACT-AAT-TGA (Seq. ID No. 7); CAT-CCA-CGA-GGA-ACG (Seq. ID No. 8); GTG-TAA-ACC-AGG-TGC (Seq. ID No. 9); ATG-GCT-CCC-AGA-ACC (Seq. ID No. 10) and GAC-AGA-ATC-GAA-GGG (Seq. ID No. 11) and sequences fully complementary thereto and of the same length.

The claims do not require a PNA probe having SEQ ID NOs 1-11- they only require a probe comprising a portion which is at least 90% homologous to one of SEQ ID NOs 1-11 or sequences fully complementary thereto.

A comparison of SEQ ID NOs 1, 2 and 3 shows no indication of any significant structural similarity.

<400> 1
agcgggtcta ttaga

<400> 2
ccaggtgagg gtcgc

<400> 3
cggttgcccg atttc

MPEP 2175.03(h) states in part that:

> The materials set forth in the Markush group ordinarily must belong to a recognized physical or chemical class or to an art-recognized class. However, when the Markush group occurs in a claim reciting a process or a combination (not a single compound), it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly responsible for their function in the claimed relationship, and it is clear from their very nature or from the prior art that all of them possess this property.

For process and combination claims, the Markush group may include members which share a common property mainly responsible for their function in the claimed relationship. It is not clear from the alignment of SEQ ID NOs 1, 2 and 3, what property, is any, that they share which is mainly responsible for their function.

Moreover, the elected invention is directed to products, not methods. While sets of probes are being claimed and will be rejoined if they require an allowable probe, the election of an individual probe having SEQ ID NO:1 is in keeping with a single compound. For compounds, unity of invention exists when the members share a common structure essential to their common utility.

MPEP 808 sets forth reasons for insisting upon restriction:

> Every requirement to restrict has two aspects: (A) the reasons (as distinguished from the mere statement of conclusion) why the inventions *as claimed* are either independent or distinct; and (B) the reasons for insisting upon restriction therebetween as set forth in the following sections.

The arguments appear to be directed to the elected invention, a probe comprising SEQ ID NO 1. These arguments are not commensurate with the invention *as claimed*. MPEP 808 explains that it is the invention, as claimed, which is considered for distinctness or

independence. It is noted that the invention *as claimed* does not require the structure of SEQ ID NO:1. Claim 10 reads upon probes which comprise a portion that is at least 90% homologous to SEQ ID NO:1. Claim 10 also encompasses in the alternative SEQ ID NOs 2-11 and complements thereof. The sets of claims 21 and 34 do not require a probe having SEQ ID NO 1. The method claims do not require a probe having SEQ ID NO 1.

Even if the products set forth in the claims were considered to have unity of invention and be eligible for election of species, any request at this point to alter examination practice is premature in view of MPEP 803.02. For election of species practice, the Office is required to consider second and subsequent species only after the elected species, as claimed, is deemed free of the prior art. As evidenced by the rejection in the latest Office action, the elected invention is still considered obvious in view of De Wachter, Kosse and Stender.

It is noted that the generic linking claim 1 which linked the probes to SEQ ID NOs 1-11 has been cancelled. Should a generic linking claim be present and found allowable, the Office would consider rejoinder of any claims which require all the limitations of an allowable generic linking claim in view of MPEP 809. It is also noted that should applicants wish to have the processes of making or using the elected product eligible for rejoinder in view of an allowable elected product claim, the process claims should be amended throughout prosecution to require all the limitations of the product claims. See MPEP 821.04.

DECISION

For these reasons, the petition to withdraw the restriction requirement is **DENIED**.

Any request for consideration must be filed within two (2) months of the mailing date of this decision.

The application will be forwarded to the examiner to consider the response filed on 26 July 2005 and to prepare an action which is consistent with this petition decision.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 571-273-8300.

Jasemine C. Chambers

Jasemine Chambers
Director, Technology Center 1600